

## REMARKS

### *Priority*

The Examiner acknowledges Applicants' claim for foreign priority based on EP02027272.0 filed December 6, 2002 and EP 03007458.7 filed April 4, 2003. However, the Examiner states that Applicants have not filed a certified copy of these applications. (Action page 2)

Applicants assert that certified copies of the EP applications were provided to the Office on February 26, 2004. Applicants attach herewith Exhibit 1, which includes a copy of the Express Mail receipt, USPTO acknowledgment postcard and a Communication as transmitted to the USPTO on February 26, 2004.

### *Information Disclosure Statement*

The Examiner has noted that the Information Disclosure Statement filed April 7, 2006, fails to comply with 37 C.F.R. 1.98(a)(2); specifically, complete copies of references numbers 11 (Humar) and 19 (Reid) were not provided. (Action page 2) Applicants submit that these references were provided with the original April 7, 2006 filing; however the text appears to have been cut off on the right margin and is incomplete. Applicants regret the administrative error. In the Information Disclosure Statement Form-1449 filed herewith, Applicants provide complete copies of both references.

The Examiner has noted that the Information Disclosure Statement filed April 7, 2006, fails to comply with 37 C.F.R. 1.98(a)(3); specifically, reference number 16 (Pelloux, which is in French) did not include a concise explanation of the relevance of the publication. (Action page 2) Applicants provide, below, the English language abstract of the Pelloux reference. An English language translation of the full article is not available; determination of the relevance of the reference is understood to have been made based on the English language abstract. The Pelloux publication teaches a DNA probe test for detection of *Legionella* in samples which is related to the subject of the teachings of the instant invention.

Seventeen suspension of *Legionella pneumophila* and ten of *Legionella bozemanii* in saline or bronchoalveolar lavage (BAL) fluid were tested using the Gen Probe technique. The detection threshold was found to be 10(3)-10(4) CFU/ml. Specificity and sensitivity were

evaluated by using the probe on 8 suspensions of bacteria other than *Legionella* and by performing a comparative study of the probe test, direct immunofluorescence and culture with 103 specimens (BAL fluid in most instances) from 92 patients with possible legionellosis. Sensitivity was found to be acceptable (3 of the 4 culture-positive specimens were positive by the probe test) and specificity was 100% despite the fact that most (80/99) BAL specimens were not sterile and regardless of the cutoff level used to define positivity. The advantages of the DNA probe test, including rapidity, simplicity and objectivity, should be weighed against its disadvantage, i.e., only acceptable sensitivity and use of radioactivity.

The Examiner has noted that the Information Disclosure Statement filed May 23, 2005, also fails to comply with 37 C.F.R. 1.98(a)(3); specifically, references numbers 11 (WO 97/07238, which is in German) and 15 (WO 01/48237 A2, which is in German) did not include concise explanations of the relevance of the patents which are not in the English language. (Action page 3) In the Information Disclosure Statement Form-1449 filed herewith, Applicants provide the English language (US patent publication) equivalents of each of the German language patents:

US 2002/0115077 is the US equivalent to reference number 11 (WO 97/07238).

US 2005/0079490 is the US equivalent to reference number 15 (WO 01/48237 A2).

Applicants request consideration of the references, remarks and Information Disclosure Statement Form-1449 filed herewith.

### *Status of the Claims*

Claims 1-8 are pending. With entry of this amendment, claims 4, 7 and 8 are canceled and claims 1-3, 5 and 6 are currently amended. No new matter is added, and support for the amendments can be found throughout the application and claims as filed. For example, aspects of original claim 3 and all of claims 4, 7 and 8 are now incorporated into claim 1. Amendments to claims 1 and 2 regarding cut off values are fully supported in the application as originally filed, for example beginning on page 8 line 27 – page 9 line 17; hybridization probes are supported, for example, beginning on page 3 line 25. Monitoring of temperature dependence of hybridization is supported, for example, beginning on page 15 line 3. Other amendments are made to correct minor typographical errors, improper multiple dependencies and other informalities.

With entry of this amendment, claims 1-3, 5 and 6 are currently pending and under consideration.

#### *Claim Objections*

The Examiner has objected to claims 3-8 as being in improper form. Additionally the Examiner has objected to claims 1-2 because of informalities in punctuation. (Action page 3) Applicants have amended claims 3, 5 and 6 to remove the multiple dependencies, have amended claims 1 and 2 to delete the series of dashes, and corrected the spacing in the reference to “claim 1” in claim 2. Claims 4, 7 and 8 are canceled.

Therefore, Applicants respectfully request that the Examiner withdraw the objections.

#### *Claim Rejections – 35 U.S.C. §112*

The Examiner has rejected claims 1-2 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. (Action page 3) The Examiner asserts in part that claims 1-2 are indefinite because it is not clear how the method steps result in “analyzing the presence of a bacterial pathogen in a clinical sample”. (Action page 4)

Applicants have amended claim 1 to clarify the methods as taught by the instant invention: “said step of quantifying the amount of said nucleic acid is performed by means of amplification which is monitored in real time by means of a hybridization probe, further comprising the step of monitoring temperature dependence of hybridization”. Further, Applicants have amended claim 1 to clarify how the presence of the bacterial pathogen is determined: “wherein said amount of nucleic acid is indicative of the presence of said bacterial pathogen if it exceeds said first predetermined cut off value, and said temperature dependence of hybridization is indicative of the presence of a group of predetermined species of said bacterial pathogen”.

Additionally Applicants have amended claim 2 to clarify the terminology of the second cut off value; the term “remains under” has been changed to “is less than”. Additionally, Applicants have amended claim 2 to clarify how the absence of the bacterial pathogen is determined. The claim now reads: “said amount of nucleic acid ... is less than a second

predetermined cut off value” and “wherein said amount of nucleic acid is indicative of the absence of said bacterial pathogen if it is less than said second predetermined cut off value”.

Applicants assert that these amendments are fully responsive to the Examiner’s assertions and respectfully request withdrawal of the §112 rejections.

*Claim Rejections – 35 U.S.C. §102*

The Examiner has rejected claims 1-2 under 35 U.S.C. §102(b) as being anticipated by Angen et al. The Examiner asserts in part that Angen teaches all the steps set forth in the instant claims, and anticipates the claimed invention. (Action page 5)

Without acquiescing to the rejection, Applicants have amended claim 1 to incorporate the limitation “wherein said step of quantifying the amount of said nucleic acid is performed by means of amplification which is monitored in real time by means of a hybridization probe, further comprising the step of monitoring temperature dependence of hybridization”. Angen teaches a method comprising a 5’ nuclease assay; the Examiner has not identified any disclosure in Angen relating to methods comprising a hybridization probe which further comprises the step of monitoring temperature dependence of hybridization. Because an asserted §102 reference must contain all limitations of a claim to anticipate that claim, Angen cannot be cited as anticipating claim 1. Because claim 2 depends from claim 1, dependent claim 2 cannot be anticipated by Angen.

With entry of the amendments to claim 1 and for the reasons provided above, Applicants respectfully request the reconsideration and withdrawal of the §102(b) rejection of claims 1 and 2.

*Drawings*

The Examiner has objected to the drawings because Figure 1 contains a typographical error, referring to “sampl s” rather than “samples”. (Action page 5) Applicants herewith provide a Replacement Sheet with the corrected spelling in Figure 1. Applicants respectfully request withdrawal of the objection to the drawings.

### CONCLUSION

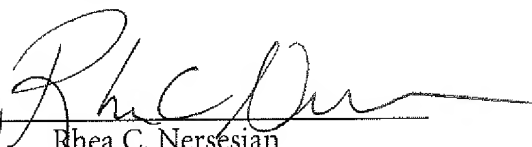
Applicants respectfully request entry of the provided Amendments and Remarks, and assert that the present application is in condition for allowance and request that the Office issue a timely Notice of Allowance. If the Examiner believes that a telephone conference would expedite prosecution of this application, please telephone the undersigned at 510-814-2908.

Applicants respectfully request a 1-month extension of time to respond to this non-final Office Action mailed June 26, 2007. The response date was September 26, 2007; with the granting of this request, the response time is re-set to October 26, 2007. The commissioner is hereby authorized to charge the amount of \$120, the fee due under 37 CFR §1.17(a)(1) to Deposit Account No. 50-0812. Please grant any additional extensions of time that may be required to enter this amendment and charge any additional fees or credit any overpayments to Deposit Account No. 50-0812.

Please direct all future correspondences to: Customer No. 22829.

Respectfully submitted,

Date: October 25, 2007

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